IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
CHARLOTTESVILLE DIVISION

CYNTHIA B. EVANS,)
)
Plaintiff,)
)
v.)
)
MEDTRONIC, INC.,)
)
Defendant,)

CASE NO. 3:04CV00097

REPORT AND RECOMMENDATION

By: B. WAUGH CRIGLER
U.S. MAGISTRATE JUDGE

Before the court are the defendant's May 16, 2005 motion for summary judgment and the defendant's June 17, 2005 motion to strike two of plaintiff's affidavits submitted in opposition to summary judgment. The motions are before the court under the authority of 28 U.S.C. § 636(b)(1)(B) to render to the presiding court a report setting forth appropriate findings, conclusions and recommendations of law for their disposition. For the reasons that follow the undersigned will recommend that an order enter GRANTING, in part, and DENYING, in part, the defendant's motion for summary judgment; and GRANTING the defendant's motion to strike from the summary judgment record the plaintiff's late-filed affidavits.

PROCEDURAL HISTORY

This products liability action arises from a spinal cord injury sustained by plaintiff on November 12, 2003 during a surgical operation at the University of Virginia Medical Center ("the Hospital"). The November 12 surgery was the last in a series of four surgeries through which Jeffrey Elias, M.D., sought to implant in plaintiff's cervical spine and upper abdomen a functional Medtronic electronic spinal cord stimulation system (technically known and referred to as the "Medtronic Itrel 3 Spinal Cord Stimulation System") to ameliorate disabling pain

plaintiff had experienced since she suffered a back injury in 1998. During the November 12 surgery, Dr. Elias discovered that the portion of the Medtronic system implanted in plaintiff's body called a "lead" had been damaged. Thereupon, he explanted (removed) that particular lead, implanted another, larger version and performed a laminectomy, in which he removed part of the plaintiff's vertebrae.

Although Dr. Elias believed the improvised operation had been successful, plaintiff awoke in severe pain and reported substantial immobility in all her extremities. Thereafter, Dr. Elias determined that plaintiff had suffered a spinal cord injury at some point during the procedure. Plaintiff's neurological condition has only slightly improved since. While she has regained some use of her arms and her right leg, she continues to experience unremitting pain in both of her upper extremities and the left side of her body; spasms, hypersensitivity and other abnormal neurological symptoms; bladder and bowel problems; and blurred vision in her left eye.

Plaintiff filed an action against Dr. Elias, alleging battery as the result of his proceeding with the laminectomy without her consent. That action was settled in July, 2004. Plaintiff also filed a products liability action against Medtronic, Inc. ("Medtronic") in the Circuit Court for Albemarle County, which Medtronic removed to federal court. On August 31, 2004, and at the request of the parties, the presiding District Judge entered an order pursuant to FED. R. CIV. P. 41(a) dismissing the case without prejudice to renew upon certain conditions, namely that the plaintiff would reinstitute any action in the United States District Court for the Western District of Virginia, that she would join no additional non-diverse parties, and that she would not seek a trial by jury. *See* Case No. 3:04CV00014 (Moon, J.), Docket # 31.

On December 17, 2004, plaintiff instituted this action against Medtronic. In her

Complaint, she alleges that the percutaneous lead implanted in her body on August 20, 2003 and found damaged on November 12, 2003 (hereafter referred to as "the Lead") was defective and unreasonably dangerous, that defendant breached its implied warranty of merchantability in that the Lead was not reasonably fit for the purpose for which it was intended, and that the defendant was negligent in manufacturing the Lead. Additionally, she alleges that, as a direct and proximate result of the discovery of the damaged and defective Lead, Dr. Elias performed a medically necessary surgery to explant the Lead and replace it with a larger Specify lead, which procedure caused plaintiff's spinal cord injury.

THE FACTUAL RECORD

The Medtronic Itrel 3 Spinal Cord Stimulation System

The Itrel 3 Spinal Cord Stimulation System ("the System") is a prescription-level medical device designed to assuage chronic pain by electronically blocking the transmission of pain signals from a patient's nerves to the brain. Defendant's Motion for Summary Judgment, Appendix ("Def's App."), Exhibit 28. The System consists of three basic parts: (1) a thin polyurethane insulated lead wire[1] with imbedded stimulating electrodes at its tip; (2) a battery-powered electronic pulse generator; and (3) a lead extension line that connects the lead to the generator.[2] *Id.* Several Medtronic leads are compatible with the Itrel 3 System, but only two of those are relevant to this case. The first is the Model 3487A "PISCES-Quad" percutaneous lead and the second is the Model 3998 "Specify" lead (also called a "surgical" lead).

The primary difference between the percutaneous lead and the surgical lead is the size of

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[1] Each lead, when manufactured, is roughly 13 inches long and 0.05 inches in dianmeter.

[2] Lead extensions are manufactured roughly 26 inches long and 0.105 inches in diameter.

their electrode tips. While the electrodes at the tip of a Medtronic percutaneous lead are nothing more than tiny metal bands wrapped around the tightly coiled inner wire, such that the electrode tip is no thicker than the lead itself, the electrodes in a Medtronic surgical lead are imbedded in a paddle shaped tip that is substantially larger than the lead wire. Def's App., Exh. 24-25. Given the smaller size of the percutaneous lead, a surgeon wishing to implant such a lead need only insert the lead wire into the subcutaneous space adjacent to the spine and thread it upward to the location of the vertebrae where stimulation is desired. Def's App., Exh. 32. The implantation of the larger surgical lead, on the other hand, requires the removal of a portion of the target vertebrae through a medical procedure known as a laminectomy. *Id.*

Once installed, both percutaneous and surgical leads operate the same way. Each is connected to an electronic pulse generator (usually implanted in a patient's abdomen) by way of a lead extension line. Def's App., Exh. 26-27. At the end of the lead extension is a two-pronged plug which fits a receptacle in the generator, much like a switch or socket in a home electrical circuit. *Id.* To fasten the lead to the lead extension, the end of the lead must be inserted into a "connector" at the tip of the lead extension and then a series of set-screws must be tightened. Def's App., Exh. 31-32. After the circuit is established, a silicone protective boot is placed over the connector and sutured to prevent bodily fluids from contaminating the connection. Def's App., Exh. 31. The fully operational system looks like a long, wire-thin snake with either a tube- or paddle-shaped head containing stimulating electrodes (depending on the type of lead), an aerodynamic bulge at its mid-section (the connector), and a semi-circular, plug-like tail (the generator).

Since the operational environment of the Itrel 3 system is the spine and abdominal tissue

of the human body, Medtronic sought to minimize its size and maximize its flexibility and durability. Def's App., Exh. 32 and 36. For instance, the insulated wire lead is made from malleable plastic and metallic materials to permit a wide range of patient movement after implantation. However, the lead is somewhat delicate and subject to failure. Def's App., Exh. 32-36. In its technical literature, Medtronic warns surgeons tasked with installing the system not to bend or kink the lead, not to tie a suture directly to the lead, not to force the lead into the epidural space, and not to over-tighten the set-screws in the connector when attaching the lead to the lead extension. Def's App., Exh. 33. The surgeon is instructed to employ only rubber-tipped bayonet forceps to manipulate the lead and is warned to be extremely careful when using sharp instruments around the lead to avoid damage. *Id.* Medtronic's Patient Management Guidelines for Clinicians and the Patient Information Booklet also warns patients with implanted stimulation systems against excessive or repetitive bending, twisting, bouncing and stretching, as such movements may shift the position of the lead and impede proper stimulation or cause damage to the lead itself. Def's App., Exh. 35-36.

Plaintiff's Pre-Operational Medical History

In February of 1998 plaintiff sustained an employment-related back injury. Def's App., Exh. 2, Plaintiff's Answers to Interrogatories ("P's Int. Ans.") at 11. Since that time, plaintiff has suffered chronic pain and numbness and has been totally disabled from work. P's Int. Ans. at 3-5. In July of 1998, plaintiff underwent surgery to correct a herniated disc, and then for the next four years she participated in a host of pain management therapies, none of which substantially

improved her condition.[3] Def's App., Exh. 9-11. In February of 2003, plaintiff was referred to Dr. Elias, a neurosurgeon at the University of Virginia Medical Center, to explore implantable spinal cord stimulation therapy. Def's App., Exh. 11. At that time, Dr. Elias was very familiar with the Medtronic spinal cord stimulation system and had performed numerous implantation surgeries using Medtronic percutaneous leads. Def's App., Exh. 38, Deposition of William Jeffrey Elias, M.D. ("Elias Dep.") at 45. Subsequent to examination, in April of 2003, Dr. Elias informed plaintiff that she was a suitable candidate for the implantation of the spinal cord stimulation system, and plaintiff elected to pursue this new course of treatment. Def's App., Exh. 11; Elias Dep. at 19-21; Pl's Int. Ans. at 5-6.

The August and September Surgeries

Prior to the November 12, 2003 surgery during which she sustained her spinal cord injury, plaintiff underwent three invasive procedures to implant and modify a Medtronic spinal cord stimulation system. On August 20, 2003, Dr. Elias conducted a trial implantation of the subject Lead in plaintiff's spinal column. After inserting the Lead into the epidural space at the C-7 vertebrae and threading it upward to C-2, Dr. Elias attached the tail end of the Lead to a temporary lead extension by way of a connector, tightened the connector set-screws, and then placed a protective silicone boot over the connector and sutured the boot in place. Def.'s App. 12-13; Elias Dep. at 35-36, 38, 158. When plaintiff reported significant pain relief, Dr. Elias decided that the system was working properly. Elias Dep. at 37, 158-160. He then anchored the Lead to the cervical fascia, a layer of connective tissue located over the muscle in the spine, and

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[3] Plaintiff was diagnosed with cervical spondylosis, a chronic degenerative condition of the cervical spine. Def's App., Exh. 9.

closed the wound to finish the surgery. *Id.*

On August 27, 2003, and after a successful one-week trial period, plaintiff was readmitted to the Hospital to undergo the surgical implantation of the remaining components of the Itrel 3 system–an electronic generator and a permanent lead extension. Def's App., Exh. 15. In this procedure, Dr. Elias reopened the cervical incision, removed the protective boot over the connector, loosened the connector set-screws, and removed the tail end of the Lead from the temporary connector. Elias Dep. at 163. After explanting the temporary connector and lead extension, Dr. Elias implanted a generator into plaintiff's abdomen and attached it to a permanent lead extension. Def's App. Exh. 15-16. He then inserted the tail end of the Lead into the permanent connector at the tip of the lead extension in precisely the same manner as he had done in the August 20, 2003 surgery. *Id.*; Elias Dep. at 64. Following this surgery, plaintiff reported a fifty percent reduction in pain. Def's App., Exh. 17.

Thereafter, plaintiff developed an infection in the tissue surrounding the generator implantation site. On September 24, 2003, she reentered the Hospital to have the generator removed and her surgical wound cleaned. Dr. Elias began the surgery by making an incision over the connector site and cutting the lead extension just below the connector. Def's App., Exh. 19. He then reopened the incision over the generator, removed it and the severed a portion of the lead extension, and irrigated both wounds with bacitracin and saline. *Id.* Having consulted with plaintiff, Dr. Elias elected to leave the Lead in place until the infection healed and a new generator and lead extension could be implanted. Def's App., Exh. 18-19.

On November 3, 2003, Dr. Elias saw plaintiff to check her wound. Def's App., Exh. 20. He noted some drainage near the area of the connector and determined that the wound would not

heal completely until the Medtronic system was revised. *Id.* Dr. Elias and plaintiff discussed the prospect of explanting the Lead and connector and starting afresh at a later date, but neither the doctor nor plaintiff preferred this remedial avenue. Instead, it was agreed that Dr. Elias would implant a new generator at a different site in plaintiff's abdomen and redirect the tail of the Lead to that location. *Id.*; Elias Dep. at 176, 181-182. This was the purpose of the November 12, 2003 surgery.

The November 12 Surgery

On November 12, 2003, plaintiff again was admitted to the Hospital under the care of Dr. Elias. Dr. Elias was assisted in the surgery by Adam S. Kanter, M.D., a resident neurosurgeon and Robin J. Hamill-Ruth, M.D., an anesthesiologist with a background in pain management and experience in the implantation of Medtronic spinal cord stimulation systems. Def's App., Exh. 21-22; Deposition of Robin J. Hamill-Ruth ("Hamill-Ruth Dep.") at 9-10. Also present at the surgery for observation purposes were two Medtronic sales representatives, John Mark Fisher and Mark Thompson. Fisher and Thompson remained outside the sterile field about five feet away from the operating table and played no role in the surgery. Deposition of John Mark Fisher ("Fisher Dep.") at 13-14.

As it is that different people often observe the same event differently, there are minor inconsistencies in the accounts of the November 12, 2003 surgery given by the various participants and spectators. Dr. Elias recalled that the resident, Dr. Kanter, commenced the surgery by prepping the patient and opening the cervical incision by which Dr. Elias originally implanted the Lead. Elias Dep. at 180-182. Dr. Elias revealed that he stepped out of the operation room prior to the cervical incision and returned after the incision had been opened. *Id.*

at 181-182. Dr. Kanter could not recall whether he performed the cervical incision. Deposition of Adam S. Kanter ("Kanter Dep.") at 25. Fisher specifically recalled Dr. Elias making the cervical incision prior to stepping out of the operating room to answer a telephone call. Fisher Dep. at 12. Thompson could not remember which doctor opened the cervical incision or when exactly Dr. Elias left the room. Deposition of Mark Thompson ("Thompson Dep.") at 15-16. Everyone agrees, however, that, in the earliest stage of the surgery, Dr. Elias exited the operating room for a brief period. Elias Dep. at 180-184; Fisher Dep. at 12; Thompson Dep. at 16.

It is further undisputed that, during Dr. Elias' absence, Dr. Kanter tugged on the Lead either with his hands or with rubber forceps, or both. Fisher Dep at 15; Thompson Dep. at 17. Fisher recalled that Dr. Kanter pulled on the exposed portion of the Lead with one hand in a repetitive pull and release fashion for some ten to fifteen seconds. Fisher Dep. at 15-16. Thompson remembered Dr. Kanter attempting to pull the lead extension up and out of the flank incision toward plaintiff's head with a pair of forceps. Thompson Dep. at 17. Both Fisher and Dr. Elias specifically recalled that the flank incision was made *after* Dr. Elias reentered the room. Fisher Dep. at 19-20; Elias Dep. at 185. Fisher also related making a comment to Thompson about the danger to the integrity of the Lead posed by Dr. Kanter's tugging. Fisher Dep. at 16-17. Fisher's comment was based upon his experience with leads that had been damaged in the past by tugging or being pulled tight. *Id.*

After Dr. Elias returned to the operating room, he explored the flank incision, likely with the assistance of a magnifying glass, in order to disconnect the Lead from the connector. Def's App., Exh. 21; Elias Dep. at 185-186. When he cut the suture ligatures and pulled the protective boot back from the tail end of the lead, Dr. Elias observed that the Silastic insulation over the

coiled wires in the lead had been breached, the coils stretched, and one of the wires broken around the point where the Lead entered the connector. Def's App., Exh. 21; Elias Dep.77-78. At his deposition, Dr. Elias testified that the Lead's insulation was "open down to the wire" but did not appear to have been cut, torn back, or peeled back. Elias Dep. at 187-188. Dr. Elias opined that the opening in the insulation was more akin to a "split." Elias Dep. at 188. Dr. Elias testified that the damage to the Lead could not have been visible until the protective boot was removed because the boot "would have covered it." Elias Dep. at 187. Of the two Medtronic observers, only Thompson was situated in such a position to view the damaged Lead. From a distance of five feet, he believed the Lead insulation to be frayed, and he could not see the split about which Dr. Elias testified. Thompson Dep. at 20-22; Fisher Dep. at 23. Thompson recalled that the damage was visible even before Dr. Elias removed the protective boot from over the connector. Thompson Dep. at 22.

Dr. Elias determined that the Lead was not salvageable and explanted it from plaintiff's spinal column along with the connector and the remaining portion of the lead extension. Dr. Elias Dep. at 79, 189-91. It is clear from Dr. Elias' testimony that he had three options at this point in the procedure: First, he could revive plaintiff and discuss the medical options available in order to determine her preferred course of further treatment. Elias Dep. at 80; Hamill Ruth Dep. at 34. Second, he could implant another PISCES-Quad percutaneous lead in place of the damaged Lead and proceed with the implantation of the generator and the lead extension, such that at the conclusion of the surgery the stimulation system would be complete. Elias Dep. at 192-193; Hamill-Ruth Dep. at 29. Third, he could implant a "resume" surgical lead or a Specify surgical lead in place of the damaged percutaneous Lead by way of a laminectomy and then proceed with

the implantation of the remainder of the stimulation system as planned.[4] Elias Dep. at 80. Dr. Elias elected to proceed with the operation and to implant a Specify surgical lead in place of the explanted percutaneous Lead. Def's App., Exh. 21; Elias Dep. at 79-80. In Dr. Elias' view, the advantages of a Specify lead over another percutaneous lead were twofold: (1) the Specify electrode would be easier to place in the same radiographic position as the original percutaneous electrode because fibrosis (scar tissue) had likely formed around the original Lead in the epidural space and could impede the reinsertion of a new percutaneous lead; and (2) the Specify lead would improve the overall coverage of the Medtronic stimulation system, and further diminish plaintiff's pain, because of the larger size of its electrode tip. Elias Dep. at 193-194.

According to Dr. Elias' postoperative report and his independent recollection, the laminectomy and the implantation of the Specify surgical lead above plaintiff's spinal cord proceeded with "much difficulty," due to fibrosis in the epidural space at the location of the original electrode. Def's App., Exh. 21; Elias Dep. at 194-195. After removing some of this scar tissue, Dr. Elias managed to thread the surgical electrode through the epidural space to the same radiographic position as the original percutaneous electrode. Def. App., Exh. 21; Elias Dep. at 83-84. At the conclusion of the surgery, Dr. Elias believed the procedure had been successful. Elias Dep. at 194-195. He did not become aware of plaintiff's postoperative complications until she regained consciousness and complained of severe pain and immobility in her extremities. Elias Dep. at 97-99. He immediately suspected that plaintiff had suffered a spinal cord injury, but this diagnosis was not confirmed until Dr. Elias received the results of a subsequent MRI,

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[4] The difference between a resume and a Specify lead is that the resume lead has one channel of electrodes, whereas the Specify lead has two channels.

which provided "visible evidence of a spinal cord injury." Elias Dep. at 107-112.

The Aftermath of the November 12 Surgery and Medtronic's Response

After Dr. Elias explanted the damaged percutaneous Lead from plaintiff's spinal cord, the Lead was discarded and never has been recovered. Elias Dep. at 89, 91; Fisher Dep. at 27-28; Thompson Dep. at 31. Dr. Elias testified that it is not his policy to save the components of explanted lead systems even though he is aware that Medtronic will not process a warranty claim without the submission of the damaged component. Elias Dep. at 89-90, 172-174. By the same token, Dr. Elias revealed that he would have taken appropriate steps to preserve the Lead had he been aware that plaintiff would make a warranty claim. Elias Dep. at 174.

A question has been raised here concerning whether either one or both of the Medtronic representatives present at the November 12 surgery had an opportunity to retrieve the damaged lead from the waste container, and, if so, whether they had a duty to secure the Lead in order to investigate into the cause of plaintiff's spinal cord injury or as material evidence in potential litigation. *Id.* As a factual matter, it is undisputed that neither Fisher nor Thompson attempted to retrieve the Lead. Fisher admitted that, at the time of the surgery, he did not believe that Medtronic's warranty covered a lost or misplaced lead. Fisher Dep. at 28-30. Fisher stated that he opted not to retrieve the Lead for two reasons: (1) Dr. Elias never suggested that the Lead might be defective, and (2) it was the responsibility of the Hospital or the plaintiff, as owner of the damaged Lead, to preserve it for any future warranty claim. Fisher Dep. at 30-31. Thompson testified that, in his experience as a Medtronic representative, there had been occasions when he had asked physicians to return products to him so that the products could be tested for warranty purposes. Thompson Dep. at 33. However, Thompson denied that he had any responsibility to

retrieve the damage Lead for investigative purposes, notwithstanding a Medtronic policy requesting the return of all explanted Medtronic products for disposal. Thompson Dep. at 34-35. In Thompson's view, the damaged Lead was "hospital property still (sic)." Thompson Dep. at 35.

It is clear from the record that both Fisher and Thompson were in the Hospital when they became aware that plaintiff had suffered postoperative complications. Fisher learned of plaintiff's plight from an anesthesiologist some twenty to thirty minutes after the procedure was completed. Fisher Dep. at 34. The anesthesiologist informed Fisher that plaintiff did not have feeling in her lower extremities. Fisher Dep. at 34-35. Thompson recalled less detail from the day in question but remembered learning of plaintiff's complications "later that day" when he inquired of Dr. Elias about when the doctor wished Thompson to activate the generator. Thompson Dep. at 29. According to Thompson, Dr. Elias responded that he should wait a couple of days because plaintiff was experiencing some problems. *Id.* Upon closer examination of the phrase "later that day," Thompson testified that he learned of plaintiff's complications after her procedure but prior to the next case, which, according to his experience, was likely to have been anywhere from twenty minutes to two hours. Thompson Dep. at 30. The following colloquy then occurred:

> Q. After you found out this lady had some postop complications, did you consider trying to get ahold of that lead?
>
> A. No.
>
> Q. Did Dr. Elias and you have any conversation about maybe it would be a good idea to get the lead?
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> A. No, not that I remember.
>
> Q. Should you have asked for that lead, sir?

A. Probably.

Q. Why do you said probably?

A. In retrospect, I wish I had.

Q. Why is that?

A. Because now there's a problem and a question about the lead.

Id. at 31-32.

Plaintiff also took the confidential deposition of Vicki L. Schreiber, a medical device reporting specialist for Medtronic, subject to a Protective Order entered by the court on May 24, 2004.[5] Plaintiff's Opposition to Defendant's Motion for Summary Judgment ("P's Opp."), Exh. P. Schreiber's principal duty as a Medtronic employee is to ensure Medtronic's complete compliance with administrative regulations promulgated by the federal Food and Drug Administration ("FDA") to govern, *inter alia*, the handling of medical devices such as the Itrel 3 Spinal Cord Stimulation System. Deposition of Vicki L. Schreiber ("Schreiber Dep.") at 4-5. Schreiber testified that one of the FDA regulations with which Medtronic seeks to comply is codified at 21 C.F.R. § 803. Schreiber Dep. at 9. Section 803 requires a manufacturer of medical devices to report to the FDA within 30 days any incident in which information is available to the manufacturer that reasonably suggests that one of its devices may have cause or contributed to death or serious injury. P's Opp., Exh. Q. As a matter of policy, Medtronic maintains compliance with § 803 by submitting to the FDA what is called a "MedWatch Report."

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[5] The undersigned is aware of the confidential nature of Ms. Schreiber's deposition and will disclose in this opinion the testimony contained therein only to the extent that such disclosure is necessary to permit a full and fair adjudication of the issues presented by Medtronic's motion for summary judgment. *See* May 24, 2004 Protective Order ¶ 13.

Schreiber Dep. at 9. Medtronic submitted a MedWatch Report in plaintiff's case in which Medtronic implicated the Specify lead, not the damaged percutaneous Lead, in plaintiff's neurological injury. Schreiber Dep. at 9-10, 26. No supplemental MedWatch Report concerning the damaged Lead was ever submitted. Schreiber Dep. at 25-26.

Schreiber also testified that, under applicable FDA regulations, Medtronic has a duty to investigate and determine the cause of serious injuries that involve their medical devices. Schreiber Dep. at 20. Schreiber was then specifically asked whether Medtronic ever requested that the Hospital find and return the damaged Lead. *Id.* She replied in the negative and explained that, in her view, "there was no reason to believe that a serious injury had occurred with that lead." *Id.* Schreiber denied that Medtronic has a duty under FDA regulations to seek the return of a medical device involved in a serious patient injury, instead stating that "[i]t is the responsibility of the user to return it." Schreiber Dep. at 21. According to Schreiber, only when an allegedly damaged or defective product is returned to the company by a user will Medtronic analyze it to determine product quality and reliability. Schreiber Dep. at 29.

Plaintiff's Expert Evidence

According to Plaintiff's Identification of Expert Witnesses on Product Defect and Causation, she intends to rely upon the expert testimony of Douglas W. Townsend, PhD, a forensic and metallurgical engineer, on the question of product defect, the expert testimony of Dr. Elias, the neurosurgeon who performed the November 12 surgery, and David C. Urquia, M.D., an orthopedic surgeon, on the questions of causation and medical necessity. Def's App., Exh. 3. Medtronic does not dispute the qualifications of Dr. Elias but does challenge the qualifications of both Drs. Townsend and Urquia, as well as the probative value and admissibility

of their opinions. The undersigned will summarize what the record shows of both their qualifications and their opinions, in that order. The undersigned then will set forth Dr. Elias' opinion about causation and medical necessity.

A. Douglas W. Townsend, PhD

Professional Qualifications

Dr. Douglas W. Townsend holds three post-secondary degrees in metallurgy and metallurgical engineering, including a master's degree from the Massachusetts Institute of Technology and a doctorate from Queen's University. Def's App., Exh. 46. Dr. Townsend is registered as a professional engineer in Canada and states that his areas of expertise are materials failure analysis, corrosion of metals, weld failures, thermal effects on metals and stress/impact metal failures. *Id.* He testified during his deposition that his specialty is forensic engineering. Deposition of Douglas W. Townsend, PhD ("Townsend Dep.") at 5.

Dr. Townsend has been retained as a forensic engineering expert in over 80 cases in state and federal courts in the United States. Townsend Dep. at 8. Dr. Townsend testified that, as a forensic engineer, he has investigated failures involving, *inter alia*, furniture, vehicles, equipment, heating systems, cooling systems, and building systems, and also biological technologies such as mandible plates, knee joints, bone plates and spinal plates. Townsend Dep. at 10. With specific relevance to this case, Dr. Townsend testified that four years ago he investigated the failure of a spinal stimulator that had a "leak in the sheath." Townsend Dep. at 11.

Dr. Townsend testified that he could not recall any case in which he was retained as an expert but excluded from testifying by the court on grounds that his methodology failed the

threshold test set forth in *Daubert v. Merrill Dow Pharmaceuticals*, 509 U.S. 579 (1993). Townsend Dep. at 16. Defense counsel then inquired of Dr. Townsend if he remembered a case from the United States District Court for the District of Maryland called *Linda May Wells v. Ford Motor Company*, in which the judge ruled that the doctor was unqualified to testify as an expert about the failure of a seat-belt mechanism because his opinion did not meet certain *Daubert* criteria. *Id.* Dr. Townsend recalled the case but did not recall having been excluded from testifying for legal reasons. Townsend Dep. at 17.

When asked by defense counsel, Dr. Townsend testified that he had not received any special educational training or field experience with implantable spinal cord systems. Townsend Dep. at 19. Dr. Townsend admitted that what knowledge he has of the percutaneous Lead at issue in this case he derived directly and exclusively from his review of Medtronic product literature in preparation for this case. Townsend Dep. at 20. However, Dr. Townsend testified that he has extensive experience with the materials out of which the Lead is constructed, namely urethane plastic and iridium metal. *Id.*

Opinion as to Product Defect

Dr. Townsend intends to testify that "[t]he lead that was removed from [plaintiff] could not have been damaged according to the descriptions made by the various observers by tugging on it 10 to 12 inches from the connector unless it was defectively manufactured." Def. App., Exh. 45 at 4. Dr. Townsend based his opinion entirely upon (a) the deposition testimony of Dr. Elias, Mark Fisher and Mark Thompson relating to Dr. Kanter's tugging and the damage to the original Lead, and (b) a one-time tensile pull test conducted on an exemplar Medtronic PISCES-Quad percutaneous lead at a laboratory testing facility in Hatfield, Pennsylvania on August 18, 2004.

Def. App., Exh. 45. Dr. Townsend gathered that both Thompson and Fisher had observed the resident, Dr. Kanter, tugging on the lead while Dr. Elias was out of the room. *Id.* at 1. He then inferred from the combination of their perspectives that the resident must have been tugging on the lead some 10 to 12 inches from the connector and insulating boot which had yet to be exposed.[6] *Id.* Since the damaged Lead had not been preserved for inspection, Dr. Townsend attempted to design a test to simulate the forces he thought Dr. Kanter likely applied to the lead during the medical procedure. *Id.* at 2. Dr. Townsend employed a tensile pull test by which he sought to determine "the type and extent of damage that could possibly occur to an exemplar lead if that lead were pulled away from the connector." *Id.*

The tensile test was fairly simple. Dr. Townsend placed the tip of the exemplar lead provided by Medtronic in the upper jaw of a Tinius Olsen 10,000 tensile testing machine and the connector end of the lead in the bottom jaw of the machine. *Id.* The jaws initially were separated by a distance of 9 inches. *Id.* During the first pull cycle, the jaws were slowly pulled apart an additional 1.7 inches over a 15-minute period of time. The machine exerted 1.7 pounds of tensile force on the lead, which resulted in the lead stretching by 1 inch without any evidence of breakage. *Id.* During the second pull cycle, the jaws of the machine slowly were pulled apart until they reached a total separation distance of 14.2 inches, with 3.44 pounds of tensile force being exerted on the lead, at which point the polyurethane insulation broke and pulled back about

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[6] It is unclear from Dr. Townsend's report whether, in determining this distance, he relied upon Dr. Townsend's testimony that Dr. Kanter tugged at the lead from the flank incision or Fisher's testimony that Dr. Kanter tugged at the lead from the cervical incision. One may hypothesize that Dr. Townsend gave greater weight to Fisher's recollection, since the flank incision was directly over the connector and tugging from that location would have occurred closer to the connector than 10 to 12 inches.

four inches from the connector end. *Id.* at 2-3. In a third pull cycle, the jaws of the machine again were pulled apart until separated 23.7 inches by a maximum pull force of 3 pounds, at which point three of the four coiled wires broke at the base of the connector under the protective boot and unraveled at various lengths. *Id.* at 3. Dr. Townsend summarized the results of the test as follows: First, the exemplar lead's polyurethane insulation did not break until it was stretched to over 150% of its original length, and when it did break, it did not stay in place but retracted "like a fallen down sock." *Id.* Second, the coiled wires of the exemplar lead did not break until they were stretched to 250% of their original length, and when they did break, they exited the boot and stayed in plain view. *Id.* From this tensile pull test, Dr. Townsend concluded:

> The differences in the appearance of the failure of the lead that was reported during [plaintiff's] operation and the observed failure of the exemplar lead are remarkable. It appears that it would not be possible to breach the polyurethane sheath and break only one electrical wire by tugging on the lead some 10 to 12 inches from the connector and only stretch and break one wire under the insulator [read "connector] unless the lead had been defectively manufactured. If Dr. Kantor (sic) had tugged on a properly manufactured lead some 10 to 12 inches from the connector hard enough to break a wire that lead should have been stretched from a length of about 13 inches to a new length of about 27 inches which should have been noticed by all of the several observers. It also appears necessary to break the polyurethane sheath in half and tug it away from the connector before it is possible to tug hard enough on the sheath to break a wire in a properly manufactured lead. It appears to be very difficult to tug on a lead and only break one wire in a properly manufactured lead.

Id. at 3-4.

Defense counsel questioned Dr. Townsend extensively about the specifications of the tensile pull test and its sufficiency for determining product defect. In the course of his testimony, Dr. Townsend admitted that the speed of the Tinius Olsen machine was set by the operator but opined that the speed of the machine did not affect the outcome of the test. Townsend Dep. at 50-52. Dr. Townsend acknowledged that if Dr. Kanter tugged on the Lead with a pair of forceps

in the direction of plaintiff's head, the lead could have become crimped or compressed at the point of contact with the forceps. Townsend Dep. at 174. Dr. Townsend further admitted that if the Lead was twisted while tugging with forceps, the Lead could have been subjected to a torsion force, a compression force and a tensile force at a given point on the lead. Townsend Dep. at 175. He conceded that he did not duplicate any of those forces in his tensile pull test. *Id.* Dr. Townsend's explanation was that he did not have "a box full of leads" or "more time" to examine numerous variations of forces. Townsend Dep. at 158-160.

In addition, Dr. Townsend acknowledged that his test pull lasted "over half an hour" in order to allow him time to make observations, while, according to the evidence in the case, Dr. Kanter tugged on the lead for 10 to 15 seconds. Townsend Dep. at 201-202. It was Dr. Townsend's view that a jerking force repeated numerous times would produce the same failure as the steady, consistent tensile force he applied using the Tinius Olsen machine. Townsend Dep. at 204-205. Later in his deposition, however, the following colloquy between defense counsel and Dr. Townsend occurred:

> Q. So assuming no defect you employ a jerking force -- you would get a different result than employing the controlled tensile force that you employed?
>
> A. No. Basically, you don't know what result you're going to get on a jerking force.
>
> Q. Until you test it?
>
> A. Well, the only way to -- if you want to test the jerking force, get Dr. Canter (sic) to start jerking on various leads and see what his results are. You know, the only one person that can replicate the jerking that -- that Dr. Canter was exerting is Dr. Canter.
>
> Q. And, therefore, you did not replicate the jerking force Dr. Canter applied, to state the obvious?

A. No.

Townsend Dep. at 213-214.

Dr. Townsend was also asked to address whether forces *beyond* those involved in the November 12, 2003 surgery could have caused the observed damage to the Lead. Specifically, he was asked whether forces in the human body–compressive, torsional, or bending–could have caused the damage. Dr. Townsend could not rule out those other causes without an opportunity to "examine the specific evidence," namely, the failed Lead. Townsend Dep. at 87-89. Again defense counsel pursued the inquiry as follows:

> Q. So, are you telling me that you can't eliminate the possibility that forces applied to the lead between 8/20 and 11/12 caused the alleged damage? You can't eliminate those possibilities?
>
> A. Based on a reasonable engineering opinion, which is more certain than less certain, that is less certain.
>
> Q. And that means you cannot eliminate alternative causes between 8/20 and 11/12 to a reasonable degree of engineering certainty?
>
> A. Not without evidence to show that possibility. Now, there's no evidence at all; therefore, there's no evidence to indicate any possibility other than a manufacturing defect.

Townsend Dep. at 115-116.

In the end, Dr. Townsend was asked repeatedly whether he could specify when and how the damage to the Lead occurred. He finally replied: "I can't give you a time or date." Townsend Dep. at 248. When then asked, "Do you know what caused the damage?" Dr. Townsend responded: "Absent the opportunity to examine the evidence, no." *Id.*

B. David C. Urquia, M.D.

Professional Qualifications

David C. Urquia, M.D., is a 1983 graduate of the University of Virginia Medical School who did his internship and residency in general and thoracic surgery at Duke University. Def's App., Exh. 48. Dr. Urquia is board certified in orthopedic surgery and is licensed to practice in North Carolina and Virginia. *Id.* He practices medicine at the West End Orthopedic Clinic in Richmond, Virginia and teaches classes in orthopedic surgery at the Medical College of Virginia. *Id.* Since 2000, Dr. Urquia has been retained as an expert witness in at least 114 cases. Deposition of Dr. David C. Urquia ("Urquia Dep.") at 12.

Dr. Urquia testified that the only formal exposure he has had to a spinal cord stimulation system was at a medical conference in the late 1990s in which a physician gave a presentation of implantable neurostimulators. Urquia Dep. at 10-11. Dr. Urquia admitted that he has never implanted a neurostimulation system such as Medtronic Itrel 3 System, nor has he specifically consulted any patient about the implantation of such a system. Urquia Dep. at 12-13. Moreover, Dr. Urquia conceded that he is unaware whether a laminectomy procedure is required to implant a percutaneous or a surgical lead in the cervical area of the spine. Urquia Dep. at 15-16. By the same token, Dr. Urquia stated that, prior to reviewing the Medtronic product literature, he possessed some basic knowledge of the trial and permanent implantation procedures for spinal cord stimulation systems. Urquia Dep. at 14-15.

Opinion as to Causation and Medical Necessity

Based on his review of plaintiff's medical records, Dr. Urquia opined that: (1) "[t]he surgery that was performed on 11/12/03 was the direct cause of [plaintiff's] spinal cord injury[,]" and (2) "there was reasonable medical necessity to perform the surgery in question," that is, the "lead change." Def's App., Exh. 47. The following exchanges relating to causation took place

between defense counsel and Dr. Urquia during his deposition:

> Q. You said [plaintiff's partial cord injury] occurred in the surgery. What happened in the surgery which caused the damage?
>
> A. I don't think anybody knows exactly what happened. All I can say or probably anybody can say is that sometime between the start of the operation and when the patient woke up some type of neurological damage occurred, but probably no one can know exactly when in the surgery it happened.
>
> Q. Dr. Elias testified that in his opinion it occurred during the laminectomy procedure.
>
> A. Okay.
>
> Q. Would you agree or disagree with that?
>
> A. That is possible. Again, my answer stands. I don't think anybody can know with absolute certainty, with reasonable medical certainty exactly when and how the injury occurred. The laminectomy, part of the procedure would be considered the most invasive part of that operation. It certainly is -- it's a logical conclusion, but I don't know when the injury actually occurred.
>
> . . . .
>
> Q. Could putting a patient to sleep cause this type of injury?
>
> A. People have had injuries to their spinal cord being put to sleep under general anesthesia.
>
> Q. So in short, you have absolutely no idea how this injury occurred?
>
> A. I can only give you speculation. I can run through a differential list of possibilities but I cannot tell you with any reasonable degree of medical probability exactly what event produced the spinal cord injury, or maybe there was more than one event – maybe more than one event during the surgery that could have produced it.
>
> . . . .
>
> Q. Was it unlikely that the injury occurred before the percutaneous lead was removed before the laminectomy began?
>
> A. That is possible.

Q. Is it unlikely?

A. I don't know. I can't give you an idea of the relative certainty of any of the possibilities. I couldn't put a percentage of (sic) it to say whether it's likely or unlikely. All I can say is that is one possibility.

Urquia Dep. at 46-49.

In addition, it was Dr. Urquia's view that a medically necessary treatment is "a treatment or procedure that if withheld would more than likely lead to a failure of treatment [for a] particular patient . . . [I]n other words, the patient's clinical course would suffer in some way if that particular treatment or procedure was withheld." Urquia Dep. at 18-19. On the other hand, he opined that an "elective procedure," that is, a non-emergency procedure, "can be considered medically necessary or not," depending on whether "the patient would have . . . some deterioration in their final outcome" if the course of treatment at issue was not pursued. Urquia Dep. at 19, 24. Upon further inquiry, Dr. Urquia conceded that he had never received any education or training about the meaning of the term "medical necessity" and was aware of no course that teaches specific legal definitions of the term to practicing orthopedic or spinal surgeons. Urquia Dep. at 17. Dr. Urquia stated that his definition of medical necessity derived from his experience as "a practicing physician that has had more than [his] fair share of interactions with medical/legal situations." *Id.*

The doctor then applied this working definition of "medical necessity" and "elective procedure" to the case at hand. He acknowledged that each of the procedures performed by Dr. Elias in the course of plaintiff's spinal cord stimulation treatment were "elective." Urquia Dep. at 25-26. However, when asked by defense counsel whether he agreed with Dr. Elias's view that the November 12 implantation of the surgical lead in place of the damaged percutaneous Lead